#5 Election S. Bruce 2/6/04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTORS: **Claude O. Clerc, et al.** GROUP ART UNIT: **3731**

APPLICATION NO.: **10/025,669** EXAMINER: **Uyen T. Ho**

FILING DATE: **December 18, 2001**

FOR: **STENT DELIVERY APPARATUS AND METHOD**

CERTIFICATE OF MAILING

I hereby certify that this correspondence, along with any other papers indicated as being enclosed, is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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RESPONSE TO RESTRICTION REQUIREMENTS DATED DECEMBER 29, 2003

Sir:

Responsive to the two–way Restriction Requirement dated December 29, 2003, Applicant elects apparatus claims 1-14.

Responsive to the three-way species sub-restriction between Species I (Figure 5, claims 1-3, 7-19, 21), species II (Figure 8, claims 4, 5, 20) and species III (Figure 9, claims 4,6, 20), applicant elects species I.

However, applicant respectfully traverses the three-way species restriction. Specifically, the Office's assertion that species I, (Figure 5) is a species distinct from Species II (Figure 8) and III (Figure 9) is incorrect. Furthermore, the Office's assertion that there is no generic claim also is incorrect.

Even further, the Office's assertion that claims 4 and 20 belong to both species II and species III is, not only incorrect, but impossible.

The present invention is a method and apparatus for delivering a stent into a body lumen. With reference to Figures 5 and 6, a stent delivery device in accordance with the present invention includes an outer tube 203 completely surrounding an inner tube 201. Slidably engaged on the inner tube 201 between the inner tube and the outer tube 203 is a carriage assembly 211. The carriage assembly 211 includes a conical, foldable sleeve 206 extending distally from the carriage assembly 211. The carriage also engages the outer tube so that movement of the outer tube can cause the carriage and sleeve to be drawn along with the outer tube causing the carriage to slide on the inner tube under force applied from the outer tube as described more fully below.

The carriage assembly 211 and sleeve 206 are designed to make it easy for a physician to insert a self-expanding stent 205 into the lumen between the inner tube 201 and the outer tube 203. The sleeve is carried on the inner tube such that the inner tube can be positioned relative to the outer tube such that the carriage extends beyond the distal end of the outer tube and the conical sleeve can be unfolded. The distal end 207b of the sleeve 206 is large enough to make it easy for a physician to insert an end of a self-expanding stent into the sleeve. Then, the inner tube can be drawn proximally so as to cause the sleeve to be drawn into the outer tube 203 and become folded between the inner tube and outer tube. Accordingly, the stent, having an end inserted in the sleeve, also is

drawn into the outer tube, thereby capturing the stent in a radially-constricted condition within the lumen between the inner tube 201 and the outer tube 203.

When the stent is ready for release, the outer tube 203 is drawn proximally relative to the inner tube 201. *Figures 8 and 9 illustrate two alternative designs that permit the outer tube 203 to apply a greater force to the carriage 211 than the frictional force between the carriage and the inner tube 201 so that the carriage 211 will be drawn proximally along with the outer tube 203 when the outer tube is drawn proximally, even though the carriage is frictionally engaged with the inner tube. Since the carriage 211 is slidable on the inner tube and proximal of the blocking element, it will slide proximally on the inner tube 201 and be drawn proximally with the outer tube 203.*

Thus, the Office has correctly identified that Figures 8 and 9, respectively, show two alternative embodiments (i.e., species) of a feature of the device, namely, the mechanism for causing the carriage to be carried along by the outer tube when it is drawn proximally, but not be carried along with the outer tube when it is pushed distally (hereinafter "the Feature"). However, Figure 5 (the alleged species I) is merely a generic drawing that simply does not illustrate the Feature at all. Claims 4 and 20, on the other hand, are dependent claims that introduce the Feature generically, i.e., claims 4 and 20 cover both the embodiments of Figures 8 and 9. Claims 5 and 6 each depend from claim 4 and recite the embodiment of Figure 8 (leaf spring) and the embodiment of Figure 9 (barbs), respectively (thus, by definition, making claim 4 a generic claim relative

to claims 5 and 6). Applicant agrees that claims 5 and 6 claim two different species of the feature introduced by claim 4.

The alleged species I corresponds to figures and claims that simply do not pertain to the feature at issue (technically making them generic claims, but actually making them essentially irrelevant to the feature at issue in connection with the species restriction). Furthermore, while claim 4 does, in fact, pertain to the Feature, it is a generic claim to the Feature.

Thus, regardless of all substance, merely the flow of dependency of the claims makes the Office's allegations in the species restriction technically impossible. Specifically, the claims that the Office has asserted correspond to species II (claims 4, 5, 20) and species III (claims 4, 6, 20) are dependent claims that depend from claims that allegedly correspond to species I (claims 1-3, 7-19 and 21). Thus, by definition, they cannot claim a species different from species I. Hence, the restriction between species I, on the one hand, and species II and III, on the other hand, is prima facie incorrect because it is impossible for there to be a species restriction between a claim and a claim that depends from it.

Additionally, species II and III are mis-defined since both include claims 4 and 20 because it is impossible for a claim to belong to two different species.

Claims 4 and 20 generically recite the Feature. Claim 5 depends from claim 4 and recites that this is accomplished by a leaf spring type design (Figure 8), while claim 6 also depends from claim 4 and recites that this is accomplished by a barbed surface type design (Figure 9). Accordingly, the only species issue is between Figure 8 (claim 5) and Figures 9 (claim 6).

In short, (1) claims 1-3, 7-19 and 21 simply do not contain any recitation relating to the Feature, (2) claim 4 is a generic claim to the Feature (encompassing both disclosed embodiments), (3) claim 5 is directed to the Figure 8 embodiment of the Feature, and (4) claim 6 is directed to the Figure 9 embodiment of the Feature. Hence, with respect to the Feature identified by the Office as relevant to the species restriction, claims 1-4, and 7-21 are generic. The only potential species restriction with respect to this feature is between claims 5 and 6.

If the Office maintains the existing three-way species restriction requirement, Applicant elects species I. Claims 1-21 correspond to species I.

Respectfully submitted,

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